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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/462,576	05/25/2000	DAPHNA HAVKIN-FRENKEL	13253-00001	5251

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EXAMINER

COLLINS, CYNTHIA E

ART UNIT PAPER NUMBER

1638

DATE MAILED: 11/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/462,576

Applicant(s)

HAVKIN-FRENKEL ET AL.

Examiner

Cynthia Collins

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on August 16, 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,4-7,31-34 and 41-44 is/are pending in the application.
- 4a) Of the above claim(s) 41-43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,4-7,31-34 and 44 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed August 16, 2004 in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 11, 2003 has been entered.

Claims 3, 8-30 and 35-40 are cancelled.

Claims 1, 4, 5, 6, 7, 31 and 32 are currently amended.

Claim 44 is newly added.

Claims 1-2, 4-7, 31-34 and 41-44 are pending.

Claims 41-43 are withdrawn.

Claims 1-2, 4-7, 31-34 and 44 are examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

Claim 7 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. Claim 7 recites "about 30 ug/ml glycosylated lysozyme". The

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limitation "about 30 ug/ml" in reference to the amount of glycosylated lysozyme used to supplement the culture does not find support in the specification as originally filed and thus constitutes new matter.

Claims 4-7 and 31-34 remain rejected, and claim 44 is rejected, under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method for producing vanillin in cultured *Vanilla planifolia* cells by supplementing the culture with 3% malic acid alone, 1 mM 3,4-dihydroxybenzaldehyde alone, or 30 ug/mL glycosylated lysozyme elicitor protein alone, does not reasonably provide enablement for making *Vanilla planifolia* cells that produce the claimed amounts of vanillin in a culture medium supplemented with any unspecified amount of malic acid, 3,4-dihydroxybenzaldehyde or glycosylated lysozyme elicitor, or for methods wherein malic acid is added to the culture medium at a concentration of between about 1% and 3% by weight after subjecting the culture to mechanical shear stress, for the reasons of record set forth in the office action mailed August 11, 2003.

Applicant's arguments filed December 11, 2003, have been fully considered but they are not persuasive.

Applicant maintains that the grounds of rejection are both legally and scientifically improper as the skilled artisan can readily make the combinations from what is known in the art. Applicant also maintains that the previously submitted Yin reference is more germane to the prosecution of the instant claims than the Rao reference cited by the Examiner, submits that the prior office action applies a double standard with respect to relevance. Applicant further

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maintains that the amendment eliminating the combinations at issue in the claims should overcome the rejection (reply pages 5-6).

The Examiner maintains that the grounds of rejection are both legally and scientifically proper. The Examiner also maintains that the outstanding rejection was not predicated on the ability of the skilled artisan to make the combinations, but on the unpredictability of the effect of the combinations on vanillin production in cultured *Vanilla planifolia*. The Examiner additionally maintains that the Yin reference is not more germane to the prosecution of the instant claims than the Rao reference, and that a double standard was not applied in the prior office action, because the Yin reference is directed to the employment of a statistical-based experimental design to evaluate the effect of different variables on the yield of tRNA in an vitro system, whereas the Rao reference is directed to the production of vanillin using *Vanilla planifolia* cell cultures, and to the effect of various compounds, including phytohormones and vanillin precursors, on vanillin production by cultured *Vanilla planifolia* cells. The rejected claims do not require, and the specification does not disclose, the employment of a statistical-based experimental design to evaluate the effect of different variables on the yield of tRNA in an vitro system, or the employment of a statistical-based experimental design to evaluate the effect of different variables on the yield of vanillin in vivo in cultured *Vanilla planifolia*. Further, while Rao et al. do not refer to malic acid, 3,4-dihydroxybenzaldehyde, or glycosylated lysozyme in particular, Rao et al. do refer to the unpredictability of using vanillin precursors other than 3,4-dihydroxybenzaldehyde (as well as the unpredictability of using phytohormones) on vanillin production by cultured *Vanilla planifolia* cells.

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The Examiner further agrees that the amendment of claim 1 eliminating the combinations at issue overcomes the rejection with respect to claim 1 and claim 2 dependent thereon, and the rejection is hereby withdrawn with respect to these two claims. The rejection is maintained, however, for claims 4-7 and 31-34, and is extended to newly added claim 44, as these claims continue to be directed to culture conditions which are not enabled.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claim 1 is missing the essential step of producing vanillin in cultured *Vanilla planifolia*. The claimed method does not result in vanillin production in cultured *Vanilla planifolia* as set forth in the preamble of the claim.

Claims 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear at what point during the method the culture is supplemented with 3,4-dihydroxybenzaldehyde, glycosylated lysozyme, succinic acid, oxaloacetic acid, citric acid and pyruvic acid, as the culture may be supplemented at more than one point during the method (i.e. upon provision of the culture in step a), and/or upon subsection of the culture to mechanical shear stress in step b)).

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the

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invention. Claim 6 is indefinite in the recitation of "The method of claim 4 wherein the culture is further supplemented". The limitation "further supplemented" lacks antecedent basis as the culture in claim 4 is not "supplemented".

Claim Rejections - 35 USC § 102

Claims 31-32 and 34 remain rejected, and claims 33 and 44 are rejected, under 35 U.S.C. 102(b) as being anticipated by Knuth et al. (US 5,057,424, 15 October 1991, Applicant's IDS), for the reasons of record set forth in the office action mailed August 11, 2003, and for the reasons set forth below.

Applicant's arguments filed December 11, 2003, have been fully considered but they are not persuasive.

Applicant argues that the cells taught by Knuth et al. do not anticipate the claimed cells because Knuth et al. do not provide any data for their cultures at day 15 after exposure to the elicitor, and because the concentration of elicitor used in the instant invention is at least 10 to 3000 times greater than that taught by Knuth et al. Applicant argues that it cannot be said that the cultures taught by Knuth et al. would necessarily produce vanillin at two or ten times the amount of a control culture as Knuth et al. is not enabling for such a culture, since Knuth et al. does not teach the range of elicitor used by Applicant, or Applicant's exposure time (reply page 7).

In response to Applicant's argument that the references fail to show certain features of Applicant's invention, it is noted that the features upon which Applicant relies (i.e., the concentration of elicitor used) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the

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claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). While the claims recite the amount of vanillin that would be produced by *Vanilla planifolia* cells after a specified period of time in the culture medium, the claims place no limitations on the amount of elicitor present in the culture medium, or on other culture conditions, needed to achieve the desired affect. Accordingly the claims read on any cell culture of *Vanilla planifolia* cells in a culture medium supplemented with any of the recited elicitors at any concentration. Further, Knuth et al. also teach embryo cells as recited in claim 33 (column 7 lines 15-29; column 13 Table 1; column 14 lines 52-63).

Remarks

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia Collins whose telephone number is (571) 272-0794. The examiner can normally be reached on Monday-Friday 8:45 AM -5:15 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on (571) 272-0804. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cynthia Collins
Examiner
Art Unit 1638

CC

Cynthia Collins 10/29/04